



1615 | Pa

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**FIRST CLASS MAIL CERTIFICATE**

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, First Class Mailed under the provisions of 37 CFR 1.8.

Candace White

April 10, 2006  
Date of Mailing

**INFORMATION DISCLOSURE STATEMENT IN  
U.S. PATENT APPLICATION NO. 10/563,031**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO/SB/08A. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Respectfully submitted,



---

Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicants

**INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW**  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4258-117

**Enclosures:**

**Confirmation Return Postcard**  
**IDS Form [2 pg(s).]**  
**Foreign Patent References [171 pgs.]**  
**Nonpatent References [88 pgs.]**

<p>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</p>
--



PTO/SB/08a (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**Substitute for form 1449A/PTO**

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

				Complete if Known	
Substitute for form 1449A/PTO				Application Number	10/563,031
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Filing Date	12/30/2005
(Use as many sheets as necessary)				First Named Inventor	Alonso Fernandez, et al.
Sheet	1	of	2	Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
				Attorney Docket Number	4258-117

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

<b>Examiner Signature</b>		<b>Date Considered</b>	
-------------------------------	--	----------------------------	--

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>2</sup>Applicant's unique citation designation number (optional). <sup>3</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>4</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
				<i>Application Number</i>	10/563,031
				<i>Filing Date</i>	12/30/2005
				<i>First Named Inventor</i>	Alonso Fernandez, et al.
				<i>Art Unit</i>	Not yet assigned
				<i>Examiner Name</i>	Not yet assigned
Sheet	2	of	2	Attorney Docket Number	4258-117

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	AH	BLANCO, M.D., ET AL., Development and characterization of protein-loaded poly(lactide-co-glycolide) nanospheres, Eur. J. Pharm. Biopharm., June 1997, Page(s) 287-294, Volume 43, Number 3
	AI	BLANCO, DOLORES, ET AL., Protein encapsulation and release from poly(lactide-co-glycolide) microspheres: effect of the protein and polymer . . . , Eur. J. Pharm. Biopharm., May 1998, Page(s) 285-294, Volume 45, Number 3
	AJ	HAWLEY, ANN E., ET AL., Lymph node localisation of biodegradable nanospheres surface modified with poloxamer and poloxamine block co-polymers, FEBS Letters, January 6, 1997, Page(s) 319-323, Volume 400, Number 3
	AK	KABANOV, ALEXANDER V., ET AL., Pluronic® block copolymers as modulators of drug efflux transporter activity in the blood-brain barrier, Adv. Drug Deliv. Rev., January 21, 2003, Page(s) 151-164, Volume 55, Number 1
	AL	LEMIEUX, P., ET AL., A combination of poloxamers increases gene expression of plasmid DNA in skeletal muscle, Gene Therapy, June 2000, Page(s) 986-991, Volume 7, Number 11
	AM	LOURENCO, CHRISTINA, ET AL., Steric stabilization of nanoparticles: Size and surface properties , Int. J. Pharm., July 12, 1996, Page(s) 1-12, Volume 138, Number 1
	AN	MOGHIMI, S.M., ET AL., Surface engineered nanospheres with enhanced drainage into lymphatics and uptake by macrophages of the regional lymph. . . , FEBS Letters, May 9, 1994, Page(s) 25-30, Volume 344, Number 1
	AO	SANCHEZ, ALEJANDRO, ET AL., Development of biodegradable microspheres and nanospheres for the controlled release of cyclosporin A, Int. J. Pharm., October 15, 1993, Page(s) 263-273, Volume 99, Number 2-3
	AP	SANCHEZ, ALEJANDRO, ET AL., Biodegradable micro- and nanoparticles as long-term delivery vehicles for interferon-alpha, Eur. J. Pharm. Sci., March 2003, Page(s) 221-229, Volume 18, Number 3-4
	AQ	TOBIO, MARIA, ET AL., A Novel System Based on a Poloxamer/ PLGA Blend as a Tetanus Toxoid Delivery Vehicle, Pharm. Res., May 1999, Page(s) 682-688, Volume 16, Number 5

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.